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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/333,256 06/15/99 ENGEL

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EXAMINER

TRAN, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

09/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/333,256

Applicant(s)  
Engel et al.

Examiner  
Susan Tran

Art Unit  
1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 9, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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### **ATTACHMENT**

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99, Requested for Extension of Time filed 08/28/00 and 05/07/01, Amendment A filed 08/28/00, Amendment B filed 10/24/00, and Notice of Appeal filed 05/07/01.

#### ***Continued Prosecution Application***

1. The request filed on 07/09/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/333,256 is acceptable and a CPA has been established. An action on the CPA follows.

#### ***Claim Rejections - 35 U.S.C. § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. US 5,905,149.

Battistini discloses a film-coated tablet composition comprising diluents, e.g., lactose, corn starch, or cellulose; lubricants, e.g., magnesium stearate, silica; and binding agents, e.g.,

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starches, or cellulose (column 11, lines 1-30). The composition further comprising antitumor agent, e.g., cyclophosphamide (column 12, lines 4-8).

Regarding to claims 4-6, it is the position of the examiner that no criticality is seen in the amounts of the ingredients since the reference obtains the same result desire by the applicant, e.g., a film coated tablet comprising cyclophosphamide, non-preswollen binding agent, lubricant, filler, and flow regulator.

***Claim Rejections - 35 U.S.C. § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al., in view of Eugster et al. US 5,593,691.

Battistini is relied upon for the reasons stated above. Regarding to claims 4-6, the cited reference is silent as to the teaching of the amounts of the ingredients.

Eugster teaches a coated tablet composition comprising active agent; excipient, filler; binder such as corn starch; flow-control; talc or magnesium stearate (column 21, lines 32 through column 22, lines 1-11). The active agent is an antitumor agent, e.g., cyclophosphamide (column 11, lines 54-56). The amounts of the ingredients are disclosed in column 32, lines 30-35. Thus,

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it would have been prima facie obvious for one of the ordinary skill in the art to modify Battistini's tablet composition using the amounts for the ingredients in view of the teaching of Eugster. The reason for this modification is to obtain a stable film coated tablet of cyclophosphamide.

The exclusion of preswollen starch does not impart patentable distinct, since the prior art obtains the same results desired by applicants, i.e., a coated tablet containing phosphamide having excellent stability and bioavailability. Thus, it would have been obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable type of starch to obtain a stable composition of phosphamide, since phosphamide is known to the skill in the art to be an unstable active compound.

#### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Van Lengerich, and Gallian et al. are cited as being of interest for the teaching of a stable film coated pellet containing phosphamide.

#### ***Response to Arguments***

4. Applicant's arguments filed 05/07/01 have been fully considered but they are not persuasive. The examiner maintains the original rejection.

In response to applicant's argument that Battistini fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., stable sources

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of cyclophosphamide) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the burden is placed upon the applicant to establish that Battistini's cyclophosphamide formulation is not a stable formulation.

Applicant argues that Battistini provides no example of tablets comprising cyclophosphamide. However, Battistini is relied upon for the teaching within the four walls patent. Battistini cannot be limited to his best mode as described in the examples.

Applicant further argues that Battistini does not teach a film-coated tablet exclusive of preswollen starch, e.g. corn starch. Contrary to the applicant's argument, a review of the reference indicates in column 11, lines 1-29, wherein a film-coating tablet is disclosed. Battistini is silent as to the exclusion of preswollen starch, however, does not disclose the use of preswollen starch either. In addition, applicant's specification examples suggest the use of starch, especially example 2 (using 0.200 mg of cornstarch). Accordingly, Battistini's corn starch and applicant's corn starch is substantially equivalent.

Applicants argued that Eugster does not teach a composition excluding preswollen starch. Eugster is silent as to the exclusion of preswollen starch, however Eugster teaches the use of corn starch, not preswollen corn starch. Hence, it is the position of the examiner that Eugster's starch and applicant's starch is substantially equivalent absent the presentation of some unusual and/or unexpected result that accrues from the claimed limit since Eugster teaches the composition has

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excellent stability and bioavailability of the active substances (column 8, lines 40-48); and the use of stabilizers to improve stability of the composition (column 22, lines 5-10).

***Continued Prosecution Application***

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

All rejections made in paper number 4 are repeated and are incorporated herein by reference.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600